540.1004.CON2

UNITED STATES PATENT AND TRADEMARK OFFICE

Re: Application of: Anand BAICHWAL, et al.

Serial No.: Not yet known

Filed: Herewith

For: **CONTROLLED RELEASE INSUFFLATION CARRIER FOR MEDICAMENTS**

PRELIMINARY AMENDMENT

Hon. Assistant Commissioner for Patents
Washington, D.C. 20231

January 14, 2002

Sir:

Please amend the above-referenced application as follows:

IN THE SPECIFICATION:

On page 1, before line 3, insert - -This application is a continuation of U.S. Patent Application Serial No. 09/361,198, filed on July 26, 1999, which is a continuation of U.S. Patent Application Serial No. 08/787,762, filed on January 28, 1997, which is a divisional of U.S. Patent Application Serial No. 08/419,635, filed on April 7, 1995, now U.S. Patent No. 5,612,053.--

IN THE CLAIMS:

Please **cancel** claims 1-25 without prejudice.

"Express Mail" mailing label no EL 914449638 US
Date of Deposit January 14, 2002
I hereby certify that the documents referred to as attached therein and/or fee are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above, in an envelope addressed to: "Assistant Commissioner for Patents, Washington, D.C. 20231"

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: Samuel Blum

Please **add** the following new claims:

26. (New) A device for delivering a medicament to a patient, comprising

an output port defining a passage for dispensing controlled release particles of a cohesive composite of a medicament and a pharmaceutically acceptable carrier to a patient;

a chamber containing the cohesive composite particles of the medicament and the pharmaceutically acceptable carrier, the pharmaceutically acceptable carrier comprising xanthan gum and locust bean gum, wherein the average particle size of said cohesive composite particles is from about 0.1 to about 125 microns in diameter;

an actuator coupled to the chamber, the actuator selectively causing the cohesive composite particles to be dispensed to the patient through the passage of the output port.

27. (New) The device of claim 26, wherein said pharmaceutically acceptable carrier comprises said xanthan gum and said locust bean gum in a ratio of from about 1:3 to about 3:1.

28. (New) The device of claim 26, wherein the average particle size of said cohesive composite particle is from about 0.1 to about 10 microns.

29. (New) The device of claim 26, wherein the average particle size of said cohesive composite particle is from about 10 to about 125 microns.

30. (New) The device of claim 26, wherein the medicament to gum ratio is from about 0.5:100 to about 1:1.

31. (New) The device of claim 30 , wherein the medicament to gum ratio is from about 1:100 to about 1:2.

32. (New) The device of claim 26, further comprising from about 0.1 to about 50% by weight of a cationic cross-linking agent comprising an alkaline metal or an alkaline earth

metal sulfate, chloride, borate, bromide, citrate, acetate or lactate.

33. (New) The device of claim 32, wherein said cationic cross-linking agent is present in an amount of from about 1 to about 10% by weight.

34. (New) The device of claim 32, wherein said cationic cross-linking agent is selected from the group consisting of potassium chloride and sodium chloride.

35. (New) The device of claim 26, wherein said pharmaceutically acceptable carrier further comprises an inert saccharide diluent selected from the group consisting of monosaccharides, disaccharides and mixtures thereof.

36. (New) The device of claim 35, wherein said inert saccharide diluent is selected from the group consisting of dextrose, sucrose, galactose, lactose and mixtures thereof.

37. (New) The device of claim 26, wherein said pharmaceutically acceptable carrier further comprises a pharmaceutically-acceptable surfactant in an amount of from about 0.5 to about 3% by weight of the controlled release carrier.

38. (New) The device of claim 37, wherein said surfactant is selected from the group consisting of pharmaceutically-acceptable anionic surfactants, cationic surfactants, amphoteric (amphipathic/amphophilic) surfactants, non-ionic surfactants, and mixtures thereof.

39. (New) The device of claim 26, wherein said controlled release particles are compressed together to form a solid mass.

40. (New) The device of claim 26, wherein said controlled release pharmaceutical is suitable for delivery to the upper respiratory tract of a human patient.

41. (New) The device of claim 26, wherein said controlled release pharmaceutical is

suitable for oral insufflation therapy.

42. (New) The device of claim 26, wherein said cohesive composite is in the form of a granulate.

REMARKS

Claims 1-25 have been deleted. New claims 26-42 have been added. No new matter has been added by virtue of this amendment. Support for the new claims may be found throughout the specification and claims as filed.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: _____

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